Initial Approval: April 12, 2012

Revised Date: April 8, 2015; July 9, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Kalydeco® (ivacaftor)

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: The following drug(s) require prior authorization:

Ivacaftor (Kalydeco)

CRITERIA FOR Kalydeco: (must meet all of the following)

Patient must be at least 2 years old.

Patient must have a diagnosis of cystic fibrosis.

- Patient must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H
- Patient must not be homozygous for the *F508del* mutation in the CFTR gene.

LENGTH OF APPROVAL: 12 months

*Note: Providers may be referred to the Cystic Fibrosis Foundation website for information regarding genetic testing to patients with a confirmed diagnosis of cystic fibrosis:

http://www.cff.org/treatments/Therapies/Kalydeco/#Is Kalydeco only for G551D.